

Attorney Docket No.: **ISPH-0567**  
Inventors: **Bennett et al.**  
Serial No.: **09/938,048**  
Filing Date: **August 23, 2001**  
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#### **REMARKS**

Claims 1, 2, 4-8, 10 and 11 are pending in the instant application. Claims 1, 2, 4-8, 10 and 11 have been rejected. Claim 1 has been amended. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Rejection of Claims Under 35 U.S.C. 102(b)**

The rejection of claims 1, 2, 4-6, 10 and 11 under 35 U.S.C. 102(b) as being anticipated by Baker et al. (US Patent 6,080,580) has been maintained. The Examiner suggests that this patent discloses use of an antisense library targeted to TNF- $\alpha$ , a cytokine, which is involved in inflammatory responses, including adding these antisense oligonucleotides to cells and measuring expression of the TNF- $\alpha$  gene following such treatment. The Examiner has suggested that Applicants arguments are not persuasive because the recitation of identifying genes in the preamble of the claims has not been given patentable weight. Further, the Examiner suggests that each and every step of the method of the instant application is taught by the cited reference. Applicants respectfully traverse this rejection.

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In an effort to advance the prosecution of this case and to clarify the instant invention, Applicants have amended claim 1, and by dependency claims 2, 4-6, 10 and 11, to recite that the instant method involves identifying one or more genes of unknown identity that are involved in an inflammatory response. Support for this amendment can be found throughout the specification as filed, but in particular in Examples 19, 20 and 21 where it is taught that the genes involved in the various specific diseases or processes that involve inflammation are identified.

As discussed in the previous Office Action response, Baker et al. (US Patent 6,080,580) disclose the use of antisense compounds targeted to TNF- $\alpha$  for inhibition of expression of this gene in cells *in vitro*. Nowhere does this patent, however, teach a method for identifying an unknown gene involved in an inflammatory response such as claimed in the instant invention. The present method specifies contacting cells, tissues or organisms that are capable of exhibiting an inflammatory response after a stimulus has been applied with a library of antisense oligonucleotides prior to treatment with a stimulus, wherein the genes are ones that have not previously been identified as modulating the inflammatory response (i.e., genes of an unknown identity), determining which antisense oligonucleotides modulate the inflammatory response wherein the

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antisense oligonucleotides that modulate the response correspond to genes involved in inflammation, and thus identifying the unknown genes involved in inflammation. Nowhere does the patent of Baker et al. teach a method where the goal is to identify a gene of an unknown identity. In this patent, the gene is used to design oligonucleotides, the oligonucleotides are not used to identify a gene. Accordingly, this patent teaches a different method from the method of the instant invention, failing to teach the limitations of the claims as amended, and cannot anticipate the claimed invention. Withdrawal of this rejection is therefore respectfully requested.

The rejection of claims 1, 2, 7, 8, 10 and 11 under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (US Patent 5,514,788) has been maintained. The Examiner suggests that this patent discloses use of antisense targeted to various cell adhesion molecules that are involved in inflammation, specifically ICAM, VCAM and ELAM. The Examiner suggests that this patent discloses inhibition of these adhesion proteins with antisense oligonucleotides from antisense libraries as well as measurement of levels of gene expression in cells after treatment of the cells with antisense and prior to challenge of the cells with various cytokines. The Examiner further suggests that the recitation of

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identification of genes in the claim preamble has been given no patentable weight. Further, the Examiner suggests that each and every step of the method of the instant application is taught by the cited reference. Applicants respectfully traverse this rejection.

As discussed *supra*, in an effort to advance the prosecution of this case and to clearly define the instant invention, Applicants have amended claim 1, and by dependency claims 2, 7, 8, 10 and 11, to recite that the instant method involves identifying one or more genes of unknown identity that are involved in an inflammatory response. Support for this amendment can be found throughout the specification as filed, but in particular in Examples 19, 20 and 21 where it is taught that the genes involved in the various specific diseases or processes that involve inflammation are identified.

Bennett et al. (US Patent 5,514,788) disclose the use of antisense compounds targeted to ICAM, ELAM or VCAM for inhibition of expression of the genes encoding each of these cell adhesion molecules in cells *in vitro*. Nowhere does this patent, however, teach a method for identifying an unknown gene involved in an inflammatory response such as claimed in the instant invention. The present method specifies contacting cells, tissues or organisms that are capable of exhibiting an inflammatory response after a

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stimulus has been applied with a library of antisense oligonucleotides prior to treatment with a stimulus, wherein the genes are ones that have not previously been identified as modulating the inflammatory response (i.e., genes of an unknown identity), determining which antisense oligonucleotides modulate the inflammatory response wherein the antisense oligonucleotides that modulate the response correspond to genes involved in inflammation, and thus identifying the unknown genes involved in inflammation. Nowhere does the patent of Bennett et al. teach a method where the goal is to identify a gene of an unknown identity. In this patent, the gene is used to design oligonucleotides, the oligonucleotides are not used to identify a gene. Accordingly, this patent teaches a different method from the method of the instant invention, failing to teach the limitations of the claims as amended, and cannot anticipate the claimed invention. Withdrawal of this rejection is therefore respectfully requested.

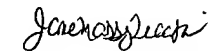
## **II. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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